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(54) Dilation catheter

(57) A dilation catheter, comprising a flexible
tube (1) provided on one end with an
expansion device and on the other end with an
activation device for the expansion device,
whereby the expansion- and the activation
devices are connected by a force transmission
device and whereby the expansion device (2),
the force transmission device (4) and the
activation device (3) are mechanically formed
and connected.



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Description

The invention concerns a dilation catheter, comprising a tube provided on one end with an expansion device and on the other end with an activation device for the expansion device, whereby the expansion and activation devices are connected by a force transmission device.

Such a dilation catheter is known. It serves for expansion of vaso- and tissue constrictions inside living people or animals with simultaneous measurement of the diameter and the forces to be used for the expansion. The expansion device in the known embodiment is formed by a balloon, which is introduced by means of the tube into the vaso- or tissue constrictions to be expanded (stenoses) and subsequently blown up. The forces to be transmitted thereby are determined by the internal pressure. The measuring accuracy is very low, because the forces necessary for an expansion of the balloon vary greatly depending on the already achieved expansion of the balloon, which is made of elastomeric material and because the elastic material of the balloon is capable of moving uncontrollably into areas which do not need expansion.

The invention is based on the problem of showing a dilation catheter which allows an exactly defined expansion of vaso- and tissue constrictions in cavities of living people or animals.

This problem is solved by the invention with a dilation catheter of the kind mentioned in the beginning with the characterizing features of claim 1. The sub-claims refer to advantageous embodiments.

In the dilation catheter according to the invention, the expansion device, the force transmission device and the activation device are mechanically developed and connected. Vaso- and tissue constrictions can thereby be much more specifically eliminated than previously, whereby the transmitted forces can be controlled with such sensitivity that the danger of injury to the tissue is clearly reduced.

The expansion device can include at least two strips located opposite to each other, which in the resting position extend essentially parallel to each other and to an imagined extension of the tube, whereby the mutual distance of the strips can be increased by means of the force transmission- and activation device. The embodiment has a very small cross section in its nonexpanded state, which facilitates introduction into narrow cavities. Nevertheless enormous increases in cross section can be achieved during the expansion of a cavity. No notable friction losses are observed therein. The forces transmitted by such an expansion device can thereby be especially sensitively recorded and measured in the area of the activating device. The operation of the dilation catheter is simple and straightforward.

A still further simplification of the operation can be achieved, if elastic devices are provided which cause a return of the expansion device to the smallest possible diameter when not being operated.

Elastic devices of this kind can be provided in the area of the expansion device, in the area of the transmission device and/or in the area of the activation device and if need be they can be changeable in their activity and/or reversible.

It has proven to be useful if several strips are distributed evenly in the circumferential direction and activated together. The force transmission device can hereby optionally consist of a rotational device or a drawbar. A drawbar has the advantage in this case, that the cross-section increase of the expansion device which is actually achieved, can be recognized and recorded very precisely in the area of the activation device. A rotational device, on the other hand, optionally allows positive or negative torsional stresses to be made useful in terms of a cross section reduction of the expansion device to an especially small diameter, or its sensitive elastic expansion with forces which remain constant over a long period of time in spite of the resulting dimensional changes and, for example, are limited to values which are compatible with tissues. The real expansion of the expansion device can thereby be recorded by means of electrical deflection gages, which constitute a component of the spring tongues and are connected with a deflection measuring device outside the body and send a signal to it.

According to one advantageous embodiment it is provided that the strips are formed by spring tongues which are supported with one end on the tube and the other end on a force transmission device which penetrates the tube, for instance a tie rod. The spring tongues are so formed, that in the inactive state the expansion device has a stretched position and the smallest possible diameter. Activation and radial expansion are caused by compression of the spring tongues between the force transmission device and the end of the tube. It results in a lateral evasive movement or bulging of the spring tongues especially in their middle area which in the sense of the invention is used as a diametrical expansion of the expansion device and to remove vasoconstrictions. In order to make a parallel expansive movement of a longer blood vessel segment possible, it has proven to be useful if the spring tongues are formed more rigidly in the middle area of their length than in the area of the ends.

Another embodiment provides that the spring tongues are woven together like wicker. A radial expansion of the diameter is possible with such an embodiment by means of relative rotation of the ends which are facing away from each other in the axial direction as well as by a mutual rapprochement of the two ends.

The strips of the expansion device can also be formed by rigid bars and be displaceably arranged transverse to the longitudinal direction of the tube. The use of such bars allows vessels to be equally expanded over a relatively large length. The bars can be supported by at least one toggle joint or an inclined plane in the tension or rotation direction. In relation to a relative displacement of the bar in a radial direction a drawbar is also advantageous for this kind of

embodiment. This can be detectable if necessary, in order to enable stabilization of

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a previously implemented expansion of a vessel. This uses the knowledge that living tissue relaxes under a static continuous load and can be expanded again after a certain period of time. While avoiding injury to living tissue, considerable vessel expansions can be achieved in this way if the total strain is distributed over a long period of time and several low amplitude strain steps.

It is also possible to bring about the dilation of a vessel very gradually and in an especially biocompatible way, with the help of motor aids which can be activated in a targeted way through control and regulation. Aids of this kind are known in other areas. Until now they have not been applied to the dilation of vessels.

The maximal cross sectional expansion of the expansion device resulting during proper use can be limited to certain values, if the rotational device or drawbar is adjustable in relation to the activation device. It can be predicted, for instance, that the drawbar would have several positions for a connection with the activation device, which could be used alternatively. It is also possible that the individual positions are developed to merge into each other without steps, and for instance are formed by various sections of a single thread, on which a support nut of the activation device is rotated. The maximum achievable expansion can be set and fixed by use of such a device before the intended use of the dilation catheter.

Normally liquids and gasses can flow through the expansion device in an axial direction, which is an advantage with respect to care of the organs, which are located behind the expansion device during correct use.

In some aspects and especially in connection with danger of injury, it can nevertheless be advantageous if the expansion device in its totality is enclosed in a stretchable, elastic sleeve which is impermeable to liquids and is sealed off by the sleeve from the tube. The sleeve can if necessary be formed from a rubber fingerstall.

The activation and expansion devices of a specific dilation catheter can be designed according to the same principle of construction and connected in such a way by the force transmission device, which in the activation device the largest diameter is present when the expansion device has the smallest diameter. Control of the cross sectional expansion resulting during correct use is especially simple with such an embodiment.

An advantageous design provides for the expansion device to be expanded in a pulsating way. The kind of generation of such a pulsating movement of the expansion device during correct use is in itself of no further significance. It can be served by electric, pneumatic and/or hydraulic aids and serves at least to allow the blood to circulate past the wall of the treated vessel, which is an advantage for the target of successful treatment.

The expansion device, the force transmission

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device and/or the activation device can be connected to at least one measuring device to record each expansion of the expansion device and/or the forces transmitted from this. An injury to the treated vessel can be better responded to hereby. Especially a simultaneous measurement of the respective diameter and the forces exercised by the expansion device is a special advantage. It reveals when a further expansion of an already strained vessel while avoiding injury to tissue is possible or when an injury to the vessel from too intensive strain has already occurred. For both aspects, it has proved to be advantageous if the measuring device is connected to a device which if necessary makes possible continuous recording of the expansion which has already been achieved and the counterforces at work on the expansion device. Thereby it is not absolutely necessary to attach the measuring device directly to the expansion device. Indirect recording of such values from the force transmission device and/or the activation device is just as possible.

It has proved to be advantageous if an empty conduit is passed through the force transmission device, the tube and the expansion device, which makes it possible to pass probes, liquids or gasses through the dilation catheter during its use, to vascular components which are located behind the expansion device. The empty conduit is correctly arranged concentric to the expansion device.

According to a further design it is provided, that the tube, the force transmission device and if applicable the empty conduit should be flexible in at least one place. Introduction of the expansion device into a hidden vascular component is hereby simplified.

The invention is explained below on the basis of the drawings. They depict:

Fig. 1 an exemplary embodiment of a dilation catheter,

Fig. 2 the dilation catheter according to Fig. 1 in a longitudinal section representation,

Fig. 3 through 7 various embodiments of expansion devices in longitudinal or cross section representation,

Fig. 8 an expansion device in a side view,

Fig. 9 an exemplary embodiment of an activation device,

Fig. 10 a dilation device similar to the embodiment according to Fig. 6 in half-cut representation, which also includes an empty conduit.

The dilation catheter shown in Fig. 1 includes a flexible tube 1, which for example could be made of hard rubber and is provided with an expansion device 2 on one end and with an activation device 3 on the other end. The dilation catheter as a whole is enveloped in a covering which is impermeable to liquids, for example a covering of natural rubber. Therefore it is especially easy to sterilize and, avoiding injury, to introduce into narrow cavities of living people or animals.

In Fig. 2 the dilation catheter according to Fig. 1 is reproduced in a longitudinal section representation. The flexible tube 1 is penetrated by a drawbar which is

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fixed between the ends of the tube determined by the expansion device 2 and the activation device 3. The other end of the expansion device 2 and the activation device 3 is supported on the front ends of the tube 1. The expansion device 2 as well as the activation device 3 consist of two spring tongues 5.1 located opposite each other in the manner depicted in Fig. 3. They are formed and united with the drawbar 4 or the tube 1 in such a way, that the expansion device 2 reaches its smallest cross section, when the expansion device 3 reaches its greatest cross section. This state is shown schematically in Fig. 2. If the spring tongues 5.1 of the expansion device 3 are compressed in the direction of the arrow, then this results in a relative displacement of the drawbar 4 relative to the tube 1 in the direction of the arrow registered there as well as a cross sectional expansion of the expansion device 2 in the direction of the arrow registered there. The expansion device 2 reaches its greatest diameter when the activation device 3 takes on its smallest diameter. By this means, the real amount of cross sectional expansion of the expansion device is sensitively controllable from outside, without the necessity to use X-rays.

Fig. 3 shows an exemplary embodiment of an expansion device of the kind applied in Fig. 2. It consists of two spring tongues 5.1, which are formed to go into each other and in their totality form a U-shaped design. The upper parts are supported on the front end of the tube 1. In the middle of the end which is distanced from this the construction is connected to the tension device 4 in a way which is resistant to pulling. On the outside of the spring tongues 5.1, bending gauges 5 are arranged. These are connected, in such a way as to give a signal, by means of connections which are not shown in the drawing, with a bending measurement device, which is located outside the body of the person or animal during correct use.

Fig. 4 shows another embodiment of the expansion device. Thereby a holder 11 is fixed to the end of the drawbar 4, which serves for axial support of the two upper ends of the spring tongues 5.1 on the front end. The other ends of the spring tongues are supported on the front end of the tube 1. On the two opposite sides of the drawbar 4 there are two spring tongues which are connected to each other, which overlap each other in the middle area of a zone which is labeled with B in Fig. 4. In the middle area the spring tongues therefore have a lower pliability than in the sections neighboring them on either side in an axial direction, which are labeled with A in Fig. 4. With a relative displacement of the drawbar 4 in regard to the tube 1 to the right, an elastic deformation of the spring tongues 5.1 results as a consequence of this, which is limited to component area A. In component area B, in contrast to this, there is almost no deformation. Also as a result of an expansion of the diameter D, the spring tongues 5.1 thereby run in area B essentially parallel to each other. For the creation of canal-like passages in vessels this is a great advantage. The expansion device is enveloped by an elastic finger stall which is impermeable to liquids, to

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avoid any contamination or injury of the treated tissue components.

In Fig. 5 an expansion device is reproduced in a cross sectional representation, in which the force transmission device is designed as a rotational device and interacts with toggle joints 7, 8, which are supported on two bars located opposite to each other 5.2. The construction is enclosed in turn in an elastic fingerstall 6 which is impermeable to liquids. A radial movement apart of the two bars 5.2 is caused by a relative rotation of the rotational device 4 to the right. This is formed by a torsionally flexible rod of metal, which permits nearly constant force to be exerted on the tissue to be expanded over a long period of time. Even changes in diameter resulting during this process have no effect on the size of this force.

In Fig. 6 an expansion device is reproduced in longitudinal section representation, with which the strips are again formed by bars located opposite to each other 5.2. These are mounted on an inclined plane 10 of a drawbar 4 and supported in such a way that they can move radially on a frontal sliding surface of the tube 1. A relative movement of the drawbar 4 in relation to the tube 1 to the right results in a cross sectional expansion of the expansion device. This is enclosed in its entirety by an elastic fingerstall 6 which is impermeable to liquids and sealed off from the tube 1.

In Fig. 7 an expansion device is reproduced in longitudinal section representation, with which the strips are formed by bars located opposite to each other 5.2, which are connected by the toggle joints 7,8 to the drawbar 4 and are supported on the front sliding surface of the tube 1. A relative displacement of the drawbar 4 to the right results in a cross sectional expansion of the expansion device.

In Fig. 8 an expansion device is reproduced in side view. The strips of this embodiment consist of spring tongues, which are woven together like wicker. The forward end of the wicker weave is connected to the force transmission device 4, the back end with the tube 1. A cross sectional expansion can be achieved with such an expansion device either through a relative rotation of the force transmission device 1 in respect to the tube 1 or by a rightward relative displacement of the force transmission device 4 in respect to the tube 1. A covering with a fingerstall for the purpose of operation is not represented in Fig. 8.

In Fig. 9 an adjustable activation device 3 for a dilation catheter is reproduced. This essentially consists of a U-shaped curved spring tongue 5.1, which is supported with the protruding end on the front end of the tube 1 and on the side away from this is pierced by an opening, through which the drawbar 4 coming from the tube 1 is passed. The drawbar 4 is provided with a thread in the area of passage through the spring tongue 5.1. A spherically shaped screw nut 12 is loosely screwed to the side of this thread of the drawbar which is away from the tube 1, and this is supported in

turn on the spring tongue 5.1. The point at which the spring tongue 5.1 is supported on the drawbar 4, can be axially shifted by a relative rotation of the screw nut 12. Depending on this, the available path to the stop contact of the drawbar 4 can be changed and hereby the value of the diameter expansion of the expansion device which is not shown in Fig. 9, can be limited to a certain value during correct use. This can be fixed before the use of the dilation catheter. Unintentional injuries are thereby especially easily prevented.

In Fig. 10 an embodiment similar to Fig. 6 is reproduced in half section representation, in which the dilation catheter as a whole is pierced by an empty conduit 13. This is formed in one piece with the draw rod and also serves as attachment for the forward end of a tube 6 which is impermeable to liquids, which encloses the expansion device and in its non active state elastically returns to its smallest diameter. Liquids, gasses or probes can be passed through the empty conduit during the correct use of the dilation tube, in order to ensure functioning of the organs located behind them, but also probes, guidewires, afterloading probes, aspiration catheter, optical devices and/or measuring devices.

Claims

1. Dilation catheter, consisting of a tube provided on one end with an expansion device and on the other end with an activation device for the expansion device, whereby the expansion and activation devices are connected by a force transmission device, **characterized by the fact that the expansion device (2), the force transmission device (4) and the activation device (3) are mechanically formed and connected.**
2. Dilation catheter as claimed in claim 1, characterized by the fact that the expansion device (2) comprises at least two strips (5) located opposite to each other, which in the resting position extend essentially parallel to each other and to an imagined extension of the tube (1) and that the mutual distance of the strips (5) can be expanded by means of the force transmission- and activation device (4, 3).
3. Dilation catheter as claimed in claims 1 and 2, characterized by the fact that several strips (5) are distributed evenly in the circumferential direction and can be jointly activated.
4. Dilation catheter as claimed in claims 1 through 3, characterized by the fact that the force transmission device (4) is formed by a drawbar or rotational device.
5. Dilation catheter as claimed in claims 1 through 4, characterized by the fact that the drawbar or rotational device is adjustable relative to the activation device (3).
6. Dilation catheter as claimed in claims 1 through 5, characterized by the fact that the strips (5) are formed by spring tongues, which are supported with one end on the tube (1) and

the other end on the drawbar or rotational device.

7. Dilation catheter as claimed in claim 6, characterized by the fact that the spring tongues (5.1) are woven together like wicker.

8. Dilation catheter as claimed in claims 6 through 7, characterized by the fact that the spring tongues (5.1) are designed to be more rigid in the middle area of their length than in the area of the ends.

9. Dilation catheter as claimed in claims 1 through 5, characterized by the fact that the strips (5) are formed by rigid bars (5.2) and can be displaced transverse to the longitudinal direction of the tube (1).

10. Dilation catheter as claimed in claim 9, characterized by the fact that the bars (5.2) are supported by at least one toggle joint (7, 8) or an inclined plain (10) on the drawbar or rotational device.

11. Dilation catheter as claimed in claims 1 through 10, characterized by the fact that the force transmission device (4) or activation device (3) is detectable.

12. Dilation catheter as claimed in claims 1 through 11, characterized by the fact that the expansion device (2) is enclosed by a stretchable, elastic sleeve (6) which is impermeable to liquids, and is sealed off by the sleeve (6) from the tube (1).

13. Dilation catheter as claimed in claims 1 through 12, characterized by the fact that at least the expansion device (2) can be connected to a measuring device and that the measuring device is designed to record each expansion of the expansion device and/or the forces transmitted from this.

14. Dilation catheter as claimed in claim 13, characterized by the fact that the measuring device includes electrical aids for determination of the measured value.

15. Dilation catheter as claimed in claims 1 through 14, characterized by the fact that the expansion device (2) can be changed to a radial pulsation.

16. Dilation catheter as claimed in claim 15, characterized by the fact that the expansion device (2) can be connected to additional pneumatic, hydraulic and/or electrical devices for the generation of pulsating radial vibration.

17. Dilation catheter as claimed in claims 1 through 16, characterized by the fact that through the force transmission device (4), the tube (1) and the expansion device (2) an empty conduit (13) is included.

18. Dilation catheter as claimed in claim 17, characterized by the fact that the empty conduit (13) concentrically penetrates the force transmission device (4), the tube (1) and the expansion device (2).

19. Dilation catheter as claimed in claims 1 through 18, characterized by the fact that the tube (1), the force transmission device (4) and if

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necessary the empty conduit (13) are flexible at
least one point in their longitudinal extension.

4 page(s) of drawings follow

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Fig.1

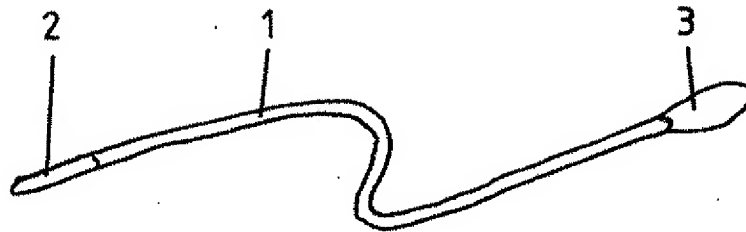
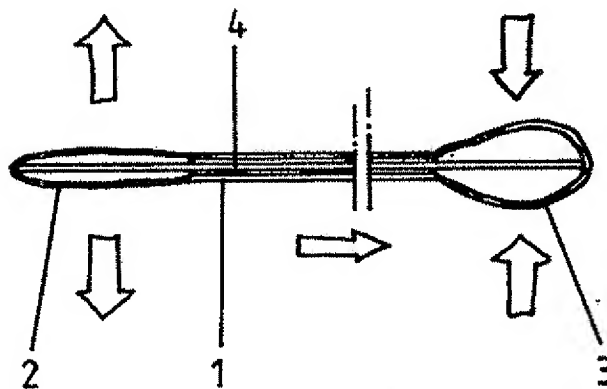
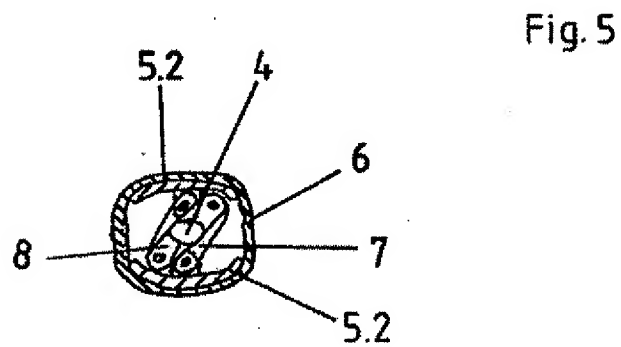
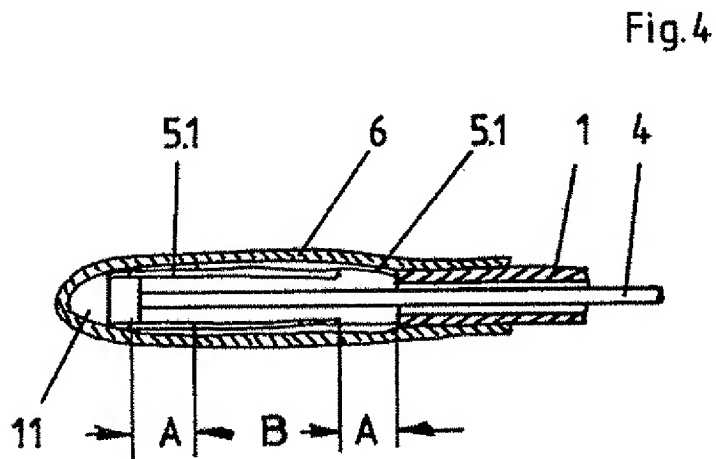
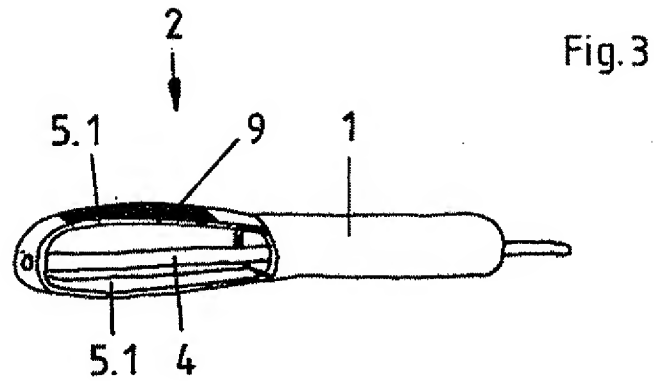


Fig.2





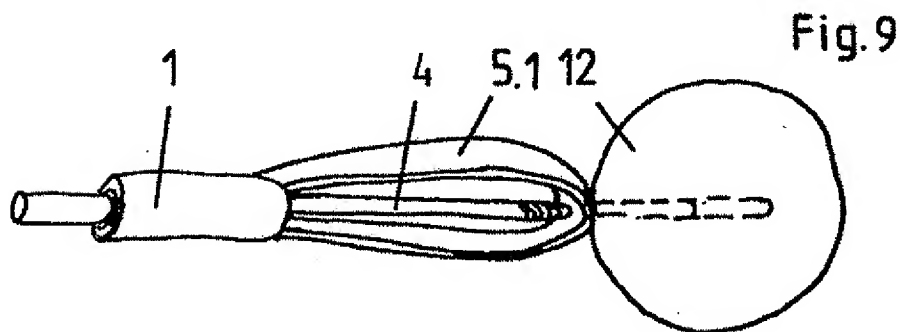
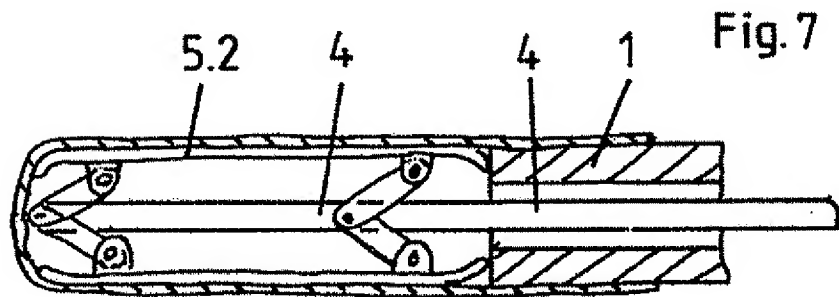
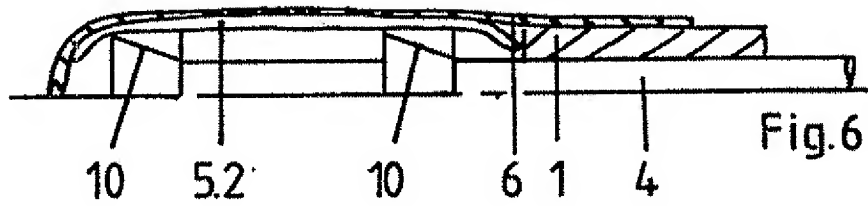


Fig. 10

